have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions.

Release into the environment. The use of a regulated article outside the constraints of physical confinement that are found in a laboratory, contained greenhouse, or a fermenter or other contained structure.

Responsible person. The person who has control and will maintain control over the introduction of the regulated article and assure that all conditions contained in the permit and requirements in this part are complied with. A responsible person shall be a resident of the United States or designate an agent who is a resident of the United States.

Secretary. The Secretary of Agriculture, or any other officer or employee of the Department of Agriculture to whom authority to act in his/her stead has been or may hereafter be delegated.

Stably integrated. The cloned genetic material is contiguous with elements of the recipient genome and is replicated exclusively by mechanisms used by recipient genomic DNA.

State. Any State, the District of Columbia, American Samoa, Guam, Northern Mariana Islands, Puerto Rico, the Virgin Islands of the United States, and any other Territories or Districts of the United States.

State regulatory official. State official with responsibilities for plant health, or any other duly designated State official, in the State where the introduction is to take place.

United States. All of the States.

Vector or vector agent. Organisms or objects used to transfer genetic material from the donor organism to the recipient organism.

Well-characterized and contains only non-coding regulatory regions (e.g. operators, promoters, origins of replication, terminators, and ribosome binding regions). The genetic material added to a microorganism in which the following can be documented about such genetic material: (a) The exact nucleotide base sequence of the regulatory region and any inserted flanking nucleotides; (b) The regulatory region and any inserted flanking nucleotides do not code for protein or peptide; and (c) The regulatory region solely controls the activity of other sequences that code for protein or peptide molecules or act as recognition sites for the initiation of nucleic acid or protein synthesis.

[52 FR 22908, June 16, 1987, as amended at 53 FR 12913, Apr. 20, 1988; 55 FR 53276, Dec. 28, 1990; 58 FR 17056, Mar. 31, 1993; 62 FR 23956, May 2, 1997]

§340.2 Groups of organisms which are or contain plant pests and exemptions.

(a) *Groups of organisms which are or contain plant pests.* The organisms that are or contain plant pests are included in the taxa or group of organisms contained in the following list. Within any taxonomic series included on the list, the lowest unit of classification actually listed is the taxon or group which may contain organisms which are regulated. Organisms belonging to all lower taxa contained within the group listed are included as organisms that may be or may contain plant pests, and are regulated *if they meet the definition of plant pest in §340.1*[4]

NOTE: Any genetically engineered organism composed of DNA or RNA sequences, organelles, plasmids, parts, copies, and/or analogs, of or from any of the groups of organisms listed below shall be deemed a regulated article if it also meets the definition of plant pest in §340.1.

[4] Any organism belonging to any taxa contained within any listed genera or taxa is only considered to be a plant pest if the organism ''can directly or indirectly injure, or cause disease, or damage in any plants or parts thereof, or any processed, manufactured, or other products of plants.'' Thus a particular unlisted species within a listed genus would be deemed a plant pest for purposes of §340.2, if the scientific literature refers to the organism as a cause of direct or indirect injury, disease, or damage to any plants, plant parts or products of plants. (If there is any question concerning the plant pest status of an organism belonging to any listed genera or taxa, the person proposing to introduce the organism in question should consult with APHIS to determine if the organism is subject to regulation.)

GROUP

VIROIDS

Superkingdom Prokaryotae

Kingdom Virus

All members of groups containing plant viruses, and all other plant and insect viruses

Kingdom Monera

DIVISION BACTERIA

Family Pseudomonadaceae
  Genus Pseudomonas
  Genus Xanthomonas
Family Rhizobiaceae
  Genus Rhizobium
  Genus Bradyrhizobium
  Genus Agrobacterium
  Genus Phyllobacterium
Family Enterobacteriaceae
  Genus Erwinia
Family Streptomycetaceae
  Genus Streptomyces
Family Actinomycetacease
  Genus Actinomyces

Coryneform group

  Genus Clavibacter
  Genus Arthrobacter
  Genus Curtobacterium
  Genus Corynebacteria
Gram-negative phloem-limited bacteria associated with plant diseases
Gram-negative xylem-limited bacteria associated with plant diseases
And all other bacteria associated with plant or insect diseases
Rickettsiaceae
  Rickettgial-like organisms associated with insect diseases

Class Mollicutes

Order Mycoplasmatales
Family Spiroplasmataceae
  Genus Spiroplasma
Mycoplasma-like organisms associated with plant diseases
Mycoplasma-like organisms associated with insect diseases

Superkingdom Eukaryotae

Kingdom Plantae

Subkingdom Thallobionta

Division Chlorophyta

  Genus Cephaleuros
  Genus Rhodochytrium
  Genus Phyllosiphon

Division Myxomycota

Class Plasmodiophoromycetes

Division Eumycota

Class Chytridiomycetes

Order Chytridiales

Class Oomycetes

Order Lagenidiales
Family Lagenidiaceae
Family Olpidiopsidaceae
Order Peronosporales
Family Albuginaceae
Family Peronosporaceae
Family Pythiaceae
Order Saprolegniales
Family Saprolegniaceae
Family Leptolegniellaceae

Class Zygomycetes

Order Mucorales
Family Choanephoraceae
Family Mucoraceae
Family Entomophthoraceae

Class Hemiascomycetes

Family Protomycetaceae
Family Taphrinaceae

Class Loculoascomycetes

Order Myriangiales
Family Elsinoeaceae
Family Myriangiaceae
Order Asterinales
Order Dothideales
Order Chaetothyriales
Order Hysteriales
Family Parmulariaceae
Family Phillipsiellaceae
Family Hysteriaceae
Order Pleosporales
Order Melanommatales

Class Plectomycetes

Order Eurotiales
Family Ophiostomataceae
Order Ascophaerales

Class Pyrenomycetes

Order Erysiphales
Order Meliolales
Order Xylariales
Order Diaporthales
Order Hypocreales
Order Clavicipitales

Class Discomycetes

Order Phacidiales
Order Helotiales
Family Ascocorticiceae
Family Hemiphacidiaceae
Family Dermataceae
Family Sclerotiniaceae
Order Cytarriales
Order Medeolariales
Order Pezziales
Family Sarcosomataceae

Family Sarcoscyphaceae

Class Teliomycetes

Class Phragmobasidiomycetes

Family Auriculariaceae
Family Ceratobasidiaceae

Class Hymenomycetes

Order Exobasidiales
Order Agaricales
Family Corticiaceae
Family Hymenochaetaceae
Family Echinodontiaceae
Family Fistulinaceae
Family Clavariaceae
Family Polyporaceae
Family Tricholomataceae

Class Hyphomycetes

Class Coelomycetes

And all other fungi associated with plant or insect diseases

Subkingdom Embryobionta

NOTE: *Organisms listed in the Code of Federal Regulations as noxious weeds are regulated under the Federal Noxious Weed Act*

Division Magnoliophyta

Family Balanophoraceae—parasitic species
Family Cuscutaceae—parasitic species
Family Hydnoraceae—parasitic species
Family Krameriaceae—parasitic species
Family Lauraceae—parasitic species
  Genus Cassytha
Family Lennoaceae—parasitic species
Family Loranthaceae—parasitic species
Family Myzodendraceae—parasitic species
Family Olacaceae—parasitic species
Family Orobanchaceae—parasitic species
Family Rafflesiaceae—parasitic species
Family Santalaceae—parasitic species
Family Scrophulariaceae—parasitic species
  Genus Alectra
  Genus Bartsia
  Genus Buchnera
  Genus Buttonia
  Genus Castilleja
  Genus Centranthera
  Genus Cordylanthus
  Genus Dasistoma
  Genus Euphrasia
  Genus Gerardia
  Genus Harveya
  Genus Hyobanche
  Genus Lathraea
  Genus Melampyrum
  Genus Melasma
  Genus Orthantha
  Genus Orthocarpus
  Genus Pedicularis
  Genus Rhamphicarpa
  Genus Rhinanthus
  Genus Schwalbea
  Genus Seymeria
  Genus Siphonostegia
  Genus Sopubia
  Genus Striga
  Genus Tozzia
Family Viscaceae—parasitic species

Kingdom Animalia

Subkingdom Protozoa

Genus Phytomonas

And all Protozoa associated with insect diseases

Subkingdom Eumetazoa

PHYLUM NEMATA

CLASS SECERNENTEA

Order Tylenchida
Family Anguinidae
Family Belonolaimidae
Family Caloosiidae
Family Criconematidae
Family Dolichodoridae
Family Fergusobiidae
Family Hemicycliophoridae
Family Heteroderidae
Family Hoplolaimidae
Family Meloidogynidae
Family Nacobbidae
Family Neotylenchidae
Family Nothotylenchidae
Family Paratylenchidae
Family Pratylenchidae
Family Tylenchidae
Family Tylenchulidae
Order Aphelenchida
Family Aphelenchoididae

CLASS ADENOPHOREA

Order Dorylaimida
Family Longidoridae
Family Trichodoridae

PHYLUM MOLLUSCA

CLASS GASTROPODA

Subclass Pulmonata
Order Basommatophora
  Superfamily Planorbacea
Order Stylommatophora
  Subfamily Strophocheilacea
Family Succineidae
  Superfamily Achatinacae
  Superfamily Arionacae
  Superfamily Limacacea
  Superfamily Helicacea
Order Systellommatophora
  Superfamily Veronicellacea

Phylum Arthropoda

Class Arachnida

Order Parasitiformes

Suborder Mesostigmata
Superfamily Ascoidea
Superfamily Dermanyssoidea
Order Acariformes
Suborder Prostigmata
Superfamily Eriophyoidea
Superfamily Tetranychoidea
Superfamily Eupodoidea
Superfamily Tydeoidea
Superfamily Erythraenoidea
Superfamily Trombidioidea
Superfamily Hydryphantoidea
Superfamily Tarsonemoidea
Superfamily Pyemotoidea
Suborder Astigmata
Superfamily Hemisarcoptoidea
Superfamily Acaroidea

Class Diplopoda

Order Polydesmida

Class Insecta

Order Collembola
Family Sminthoridae
Order Isoptera
Order Thysanoptera
Order Orthoptera
Family Acrididae
Family Gryllidae
Family Gryllacrididae
Family Gryllotalpidae
Family Phasmatidae
Family Ronaleidae
Family Tettigoniidae
Family Tetrigidae
Order Hemiptera
Family Thaumastocoridae
Family Aradidae
Superfamily Piesmatoidea
Superfamily Lygaeoidea
Superfamily Idiostoloidea
Superfamily Coreoidea
Superfamily Pentatomoidea
Superfamily Pyrrhocoroidea
Superfamily Tingoidea
Superfamily Miroidea
Order Homoptera
Order Coleoptera
Family Anobiidae
Family Apionidae
Family Anthribidae
Family Bostrichidae
Family Brentidae
Family Bruchidae
Family Buprestidae
Family Byturidae
Family Cantharidae
Family Carabidae
Family Cerambycidae
Family Chrysomelidae
Family Coccinellidae
Subfamily Epilachninae
Family Curculionidae
Family Dermestidae
Family Elateridae
Family Hydrophilidae
Genus Helophorus
Family Lyctidae
Family Meloidae
Family Mordellidae
Family Platypodidae
Family Scarabaeidae
Subfamily Melolonthinae
Subfamily Rutelinae
Subfamily Cetoniinae
Subfamily Dynastinae
Family Scolytidae
Family Selbytidae
Family Tenebrionidae
Order Lepidoptera
Order Diptera
Family Agromyzidae
Family Anthomyiidae
Family Cecidomyiidae
Family Chloropidae
Family Ephydridae
Family Lonchaeidae
Family Muscidae
Genus Atherigona
Family Otitidae
Genus Euxeta
Family Syrphidae
Family Tephritidae
Family Tipulidae
Order Hymenoptera
Family Apidae
Family Caphidae
Family Chalcidae
Family Cynipidae
Family Eurytomidae
Family Formicidae
Family Psilidae
Family Siricidae
Family Tenthredinidae
Family Torymidae
Family Xylocopidae

Unclassified organisms and/or organisms whose classification is unknown.

(b) *Exemptions.* (1) A limited permit for interstate movement shall not be required for genetic material from any plant pest contained in *Escherichia coli* genotype K–12 (strain K–12 and its derivatives), sterile strains of *Saccharomyces cerevisiae,* or asporogenic strains of *Bacillus subtilis,* provided that all the following conditions are met:

(i) The microorganisms are shipped in a container that meets the requirements of § 340.8(b)(3);

(ii) The cloned genetic material is maintained on a nonconjugation proficient plasmid and the host does not contain other conjugation proficient plasmids or generalized transducing phages;

(iii) The cloned material does not include the complete infectious genome of a known plant pest;

(iv) The cloned genes are not carried on an expression vector if the cloned genes code for:

(A) A toxin to plants or plant products, or a toxin to organisms beneficial to plants; or

(B) Other factors directly involved in eliciting plant disease (i.e., cell wall degrading enzymes); or

(C) Substances acting as, or inhibitory to, plant growth regulators.

(2) A limited permit for interstate movement is not required for genetic material from any plant pest contained in the genome of the plant *Arabiodopsis thaliana*, provided that all of the following conditions are met:

(i) The plants or plant materials are shipped in a container that meets the requirements of §340.8(b) (1), (2), and (3);

(ii) The cloned genetic material is stably integrated into the plant genome;

(iii) The cloned material does not include the complete infectious genome of a known plant pest.

[52 FR 22908, June 16, 1987, as amended at 53 FR 12913, Apr. 20, 1988; 55 FR 53276, Dec. 28, 1990; 58 FR 17056, Mar. 31, 1993]

§340.3 Notification for the introduction of certain regulated articles.[5]

(a) *General.* Certain regulated articles may be introduced without a permit, provided that the introduction is in compliance with the requirements of this section. Any other introduction of regulated articles require a permit under §340.4, with the exception of introductions that are conditionally exempt from permit requirements under §340.2(b) of this part.

(b) *Regulated articles eligible for introduction under the notification procedure.* Regulated articles which meet all of the following six requirements and the performance standards set forth in paragraph (c) of this section are eligible for introduction under the notification procedure.

(1) The regulated article is any plant species that is not listed as a noxious weed in regulations at 7 CFR part 360 under the Federal Noxious Weed Act (7 U.S.C. 2809), and, when being considered for release into the environment, the regulated article is not considered by the Administrator to be a weed in the area of release into the environment.

(2) The introduced genetic material is ''stably integrated'' in the plant genome, as defined in §340.1.

(3) The function of the introduced genetic material is known and its expression in the regulated article does not result in plant disease.

(4) The introduced genetic material does not:

(i) Cause the production of an infectious entity, or

(ii) Encode substances that are known or likely to be toxic to nontarget organisms known or likely to feed or live on the plant species, or

(iii) Encode products intended for pharmaceutical use.

(5) To ensure that the introduced genetic sequences do not pose a significant risk of the creation of any new plant virus, plant virus-derived sequences must be:

(i) Noncoding regulatory sequences of known function, or

(ii) Sense or antisense genetic constructs derived from viral genes from plant viruses that are prevalent and endemic in the area where the introduction will occur and that infect plants of the same host species, and that do not encode a functional noncapsid gene product responsible for cell-to-cell movement of the virus.

(6) The plant has not been modified to contain the following genetic material from animal or human pathogens:

(i) Any nucleic acid sequence derived from an animal or human virus, or

(ii) Coding sequences whose products are known or likely causal agents of disease in animals or humans.

(c) *Performance standards for introductions under the notification procedure.* The following performance standards

[5] APHIS may issue guidelines regarding scientific procedures, practices, or protocols which it has found acceptable in making various determinations under the regulations. A person may follow an APHIS guideline or follow different procedures, practices, or protocols. When different procedures, practices, or protocols are followed, a person may, but is not required to, discuss the matter in advance with APHIS to help ensure that the procedures, practices, or protocols to be followed will be acceptable to APHIS.